AWARD NUMBER: W81XWH-15-1-0708

TITLE: Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

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CONTRACTING ORGANIZATION: Northwestern University

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REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2016	Annual	30 Sep 2015 - 29 Sep 2016

4. TITLE AND SUBTITLE

Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0708

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This project is a clinical trial to compare the new prosthetic socket we developed (the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket) with the current standard of care socket (the Ischial Containment (IC) Socket) with the goal of demonstrating objective functional superiority as well as more desirable patient-reported outcome measures. The primary aims of the study are (1) to demonstrate if the NU-FlexSIV Socket is more comfortable than the IC Socket; (2) to demonstrate if the NU-FlexSIV Socket results in better functional performance than the IC Socket; and (3) to demonstrate if the NU-FlexSIV Socket will result in better quality of life and ''satisfaction with device'' (i.e. prosthesis) than the IC Socket. During year 1, we received all required IRB approvals, registered the clinical trial, and recruited our goal of 10 subjects (five who are actively being tested and five who are awaiting socket fitting/testing).

15. SUBJECT TERMS
Prosthetic Socket, Artificial Limbs, Prosthesis, Transfemoral Amputee, Gait, Socket Comfort

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	13	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

This project is a clinical trial to compare the new prosthetic socket we developed (the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket) with the current standard of care socket (the Ischial Containment (IC) Socket) with the goal of demonstrating objective functional superiority as well as more desirable patient-reported outcome measures. The availability of a more comfortable and functional socket will contribute to improving the quality of life of persons with transfemoral amputation. This clinical trial is an assessor-blinded prospective randomized cross-over trial wherein participants with unilateral transfemoral amputation are randomized to using one of the two socket conditions before crossing over to the other socket condition. The trial will be balanced such that all subjects will receive all treatments (i.e., both socket conditions) and that all subjects will participate for the same number of periods (i.e., two). The primary aims of the study are (1) to demonstrate if the NU-FlexSIV Socket is more comfortable than the IC Socket; (2) to demonstrate if the NU-FlexSIV Socket results in better functional performance than the IC Socket; and (3) to demonstrate if the NU-FlexSIV Socket will result in better quality of life and "satisfaction with device" (i.e. prosthesis) than the IC Socket.

2. KEYWORDS:

Prosthetic Socket, Artificial Limbs, Prosthesis, Transfemoral Amputee, Gait, Socket Comfort

3. ACCOMPLISHMENTS:

Major Objectives of the Project

Aim 1: To demonstrate if the NU-FlexSIV Socket is more comfortable than the IC socket.

Aim 2: To demonstrate if the NU-FlexSIV Socket results in better functional performance than the IC socket.

Aim 3: To demonstrate if the NU-FlexSIV Socket will result in better quality of life and "satisfaction with device" (i.e. prosthesis) than the IC socket.

Accomplishments under these Objectives

Scope of Work (SOW) Tasks	Timeline (months)	Progress to date
Major Task 1 – Recruit subjects (n=10/year)	1-36	
Subtask 1.1 – IRB approvals (NU, VA, HRPO)	1	Completed
Subtask 1.2 – Recruit subjects 1-10	1-9	Completed
Subtask 1.3 – Recruit subjects 11-20	13-21	Not yet started
Subtask 1.4 – Recruit subjects 21-30	25-33	Not yet started
Major Task 2 – Fabricate sockets	1-36	
Subtask 2.1 – Fabricate IC sockets for subjects 1-5	1-3	Completed for subjects 1 and 3, underway for subjects 2, 4 and 5

Scope of Work (SOW) Tasks	Timeline (months)	Progress to date
Subtask 2.2 – Fabricate NU-FlexSIV sockets for subjects 1-5	1-3	Completed for subjects 2 and 4, underway for subjects 1 and 3
Subtask 2.3 – Fabricate IC sockets for subjects 6-10	7-9	Subjects enrolled but not yet participating
Subtask 2.4 – Fabricate NU-FlexSIV sockets for subjects 6-10	7-9	Subjects enrolled but not yet participating
Subtask 2.5 – Fabricate IC sockets for subjects 11-15	13-15	Not yet started
Subtask 2.6 – Fabricate NU-FlexSIV sockets for subjects 11-15	13-15	Not yet started
Subtask 2.7 – Fabricate IC sockets for subjects 16-20	18-20	Not yet started
Subtask 2.8 – Fabricate NU-FlexSIV sockets for subjects 16-20	18-20	Not yet started
Subtask 2.9 – Fabricate IC sockets for subjects 21-25	25-27	Not yet started
Subtask 2.10 – Fabricate NU-FlexSIV sockets for subjects 21-25	25-27	Not yet started
Subtask 2.11 – Fabricate IC sockets for subjects 26-30	31-33	Not yet started
Subtask 2.12 – Fabricate NU-FlexSIV sockets for subjects 26-30	31-33	Not yet started
Major Task 3 – Collect data	1-36	
Subtask 3.1 – Test IC sockets for subjects 1-5	1-3	Completed data collection for subjects 1 and 3
Subtask 3.2 – Test NU-FlexSIV sockets for subjects 1-5	1-3	Completed data collection for subjects 2 and 4
Subtask 3.3 – Test IC sockets for subjects 6-10	7-9	Subjects enrolled but not yet participating
Subtask 3.4 – Test NU-FlexSIV sockets for subjects 6-10	7-9	Subjects enrolled but not yet participating
Subtask 3.5 – Test IC sockets for subjects 11-15	13-15	Not yet started
Subtask 3.6 – Test NU-FlexSIV sockets for subjects 11-15	13-15	Not yet started
Subtask 3.7 – Test IC sockets for subjects 16-20	18-20	Not yet started
Subtask 3.8 – Test NU-FlexSIV sockets for subjects 16-20	18-20	Not yet started
Subtask 3.9 – Test IC sockets for subjects 21-25	25-27	Not yet started
Subtask 3.10 – Test NU-FlexSIV sockets for subjects 21-25	25-27	Not yet started
Subtask 3.11 – Fabricate IC sockets for subjects 26-30	31-33	Not yet started
Subtask 3.12 – Fabricate NU-FlexSIV sockets for subjects 26-30	31-33	Not yet started
Major Task 4 – Process and analyze data	1-36	

Scope of Work (SOW) Tasks	Timeline (months)	Progress to date
Subtask 4.1 – Test IC sockets for subjects 1-5	1-3	Underway
Subtask 4.2 – Test NU-FlexSIV sockets for subjects 1-5	1-3	Underway
Subtask 4.3 – Test IC sockets for subjects 6-10	7-9	Not yet started
Subtask 4.4 – Test NU-FlexSIV sockets for subjects 6-10	7-9	Not yet started
Subtask 4.5 – Test IC sockets for subjects 11-15	13-15	Not yet started
Subtask 4.6 – Test NU-FlexSIV sockets for subjects 11-15	13-15	Not yet started
Subtask 4.7 – Test IC sockets for subjects 16-20	18-20	Not yet started
Subtask 4.8 – Test NU-FlexSIV sockets for subjects 16-20	18-20	Not yet started
Subtask 4.9 – Test IC sockets for subjects 21-25	25-27	Not yet started
Subtask 4.10 – Test NU-FlexSIV sockets for subjects 21-25	25-27	Not yet started
Subtask 4.11 – Fabricate IC sockets for subjects 26-30	31-33	Not yet started
Subtask 4.12 – Fabricate NU-FlexSIV sockets for subjects 26-30	31-33	Not yet started
Milestone: Publish journal article(s)	36	Not yet started

Notes on progress

During the first quarter, we applied for and received IRB approval from NU, JBVAMC and HRPO. We also recruited a statistician, Dr. Kwang-Youn Kim, to assist with statistical analyses. At his suggestion we enrolled for training and began setting up a REDCap database for data analysis. REDCap is a secure, web-based application for building and managing data for research studies. We also made progress with drafting a manual of procedures and clinical trial registration.

During the second quarter, we completed registration on clinicaltrials.gov (NCT02678247), trained Lilly Tran to administer the clinical outcome measures, and executed subcontracts with our collaborators. We also completed the manual of procedures and scheduled our team kick-off meeting.

During the third quarter, we checked and prepared the StepWatches for data collection and held our team kick-off meeting in April 2016. The kick-off meeting gave the team the opportunity to meet and review the manual of procedures. Recruitment began after this meeting. We were able to recruit the first 10 subjects relatively quickly but in order to manage workload and due to having only five StepWatches, we can only have five subjects actively participating in the study at any given time.

During the third and fourth quarters, the first five subjects have actively participated in the study and continue to do so into the second year of the grant. Lilly Tran has received training on processing of gait data.

Opportunities for Training and Professional Development
"Nothing to Report"

Dissemination of Results
"Nothing to Report"

Plans and Goals for the Next Reporting Period
There are currently ten subjects enrolled in the study, five who are actively being tested and five who are awaiting socket fitting/testing. During the next reporting period, we plan to complete testing of the first five subjects and begin testing of the next five subjects. We will also continue to recruit subjects, with special effort on recruiting Veterans. Data from the first cohort of subjects will be processed and reviewed.

4. IMPACT:
Impact on the Development of Prosthetics
We have taken every opportunity to promote the clinical trial to the prosthetics community. This process has been facilitated by the attention that our previous socket development project (#W81XWH-10-0744) has received. For example, an industry review in the magazine The O&P Edge mentioned the clinical trial and as a result we have had a couple of inquiries from both persons with amputation and prosthetists interested in participating and supporting the trial. Hence, the clinical trial has gained some visibility in the prosthetics community.

Impact on Other Disciplines
"Nothing to Report"

Impact on Technology Transfer
"Nothing to Report"

Impact on Society beyond Science and Technology
"Nothing to Report"

5. CHANGES/PROBLEMS:
Changes in Approach/Reasons for Change
"Nothing to Report"

Actual/Anticipated Problems or Delays and Actions/Plans to Resolve Them
Subject recruitment and testing began in April 2016 after all IRB approvals were received and clinical trial registration was completed. While we are behind in terms of testing, subject enrollment is on target as we were able to recruit our year 1 goal of 10 subjects within a few months of our kick-off meeting. We anticipate that the delayed start-up will likely necessitate a

no-cost extension at the end of the life of the award unless we are able to make up time by testing more subjects simultaneously. Testing is currently limited to five subjects at a time due to a limitation in the number of StepWatches available for data collection. We are exploring the possibility of borrowing loaner StepWatches from the manufacturer, Orthocare, in order to increase testing capacity. If we are able to borrow additional StepWatches, we may be able to accelerate testing and make up some of the time lost at the beginning of year 1.

Changes that had a Significant Impact on Expenditures
"Nothing to Report"

Significant Changes in Care of Human Subjects
"Nothing to Report"

6. PRODUCTS:

Publications, conference papers, and presentations

Journal publications.
"Nothing to Report"
Books or other non-periodical, one-time publications.
"Nothing to Report"
Other publications, conference papers, and presentations.
Fatone S, Caldwell R (2016) Socket-Related Research Collaborations at Northwestern University. Scheck Fair. April 8-9, Lombard, Illinois.

Website(s) or other Internet site(s)

- http://www.nupoc.northwestern.edu/research/projects/lowerlimb/FunctionalPerfEvalNUFlexSIV.html
- https://clinicaltrials.gov/ct2/show/NCT02678247

Technologies or techniques
"Nothing to Report"

Inventions, patent applications, and/or licenses
"Nothing to Report"

Other Products
"Nothing to Report"

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Individuals on the project

Name:	Stefania Fatone, PhD, BPO(Hons)
Project Role:	Principal Investigator

Researcher Identifier (e.g. ORCID ID):	0000-0002-5802-035X
Nearest person month worked:	2
Contribution to Project:	Oversees and manages all aspects of the project including IRB, subject recruitment, data collection, analysis, presentations and publications.

Name:	Steven Gard, PhD
Project Role:	Site PI (JBVAMC)
Researcher Identifier (e.g. ORCID ID):	0000-0002-4251-2464
Nearest person month worked:	1
Contribution to Project:	Oversees and manages aspects of the project occurring at the JBVAMC.

Name:	Michael Oros, CPO
Project Role:	Site PI (Scheck & Siress)
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Oversees and manages aspects of the project occurring at Scheck & Siress.

Name:	Ryan Caldwell, CP
Project Role:	Research Prosthetist
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Fabricate and fit NU-Flex Sockets to subjects.

Name:	John Angelico, CPO
Project Role:	Research Prosthetist
Researcher Identifier (e.g. ORCID ID):	N/A

Nearest person month worked:	2
Contribution to Project:	Fabricate and fit IC sockets to subjects.

Name:	Lilly Tran, MS
Project Role:	Research Engineer, blinded assessor
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Administers clinical outcome measures, processes gait data, and assists with data entry into RedCAP.

Name:	Thomas Schnitzer, PhD
Project Role:	Co-investigator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Guide and mentor PI with clinical trial processes.

Name:	Rebecca Stine, MS
Project Role:	Manager, JBVAMC-Motion Analysis Research Lab
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Collects gait data and assists with recruitment of Veteran subjects.

Name:	Marc Applebaum, MD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Recruits Veteran subjects.

Name:	Kwang-Youn Kim, PhD
Project Role:	Statistician
Researcher Identifier (e.g. ORCID ID):	0000-0002-4168-757X
Nearest person month worked:	1
Contribution to Project:	Guides statistical analysis.

Name:	RJ Garrick, PhD
Project Role:	Research Consultant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Drafted Manual of Procedures, registered clinical trial and created RedCAP database.

Drs. Fatone and Schnitzer began working on the grant in October 2015. Drs. Kim and Garrick began working on the grant in December 2015. Other personnel began working on the project in April 2016 when all IRB approvals were received, the team kick-off meeting had been held, and subject recruitment and enrollment began.

Changes in the Active Support of the PD/PI(s) or Senior/Key Personnel
"Nothing to Report"

Organizations Involved as Partners

Organization Name: Jesse Brown VA Medical Center
Location of Organization: 820 S. Damen Avenue, Chicago, IL 60612
Partner's Contribution to the Project:

- Veteran subject recruitment.
- Gait data is collected in the Jesse Brown VA Medical Center Motion Analysis Research Laboratory.

Organization Name: Scheck & Siress
Location of Organization: 1S376 Summit Avenue, Court E, Oakbrook Terrace, IL 60181
Partner's Contribution to the Project

- Subject recruitment.
- Fabrication and fitting of ischial containment sockets.

8. SPECIAL REPORTING REQUIREMENTS
See Quad Chart in Appendix.

9. APPENDICES:
Quad Chart attached.

Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

OR140372
W81XWH-15-1-0708

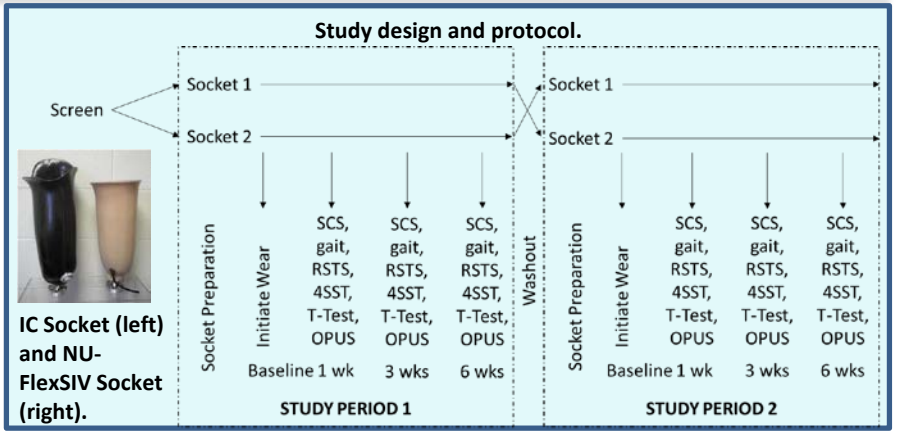
PI: Stefania Fatone **Org:** Northwestern University **Award Amount:** $1,326,755

Study Aims

- **Aim 1:** To demonstrate if the NU-FlexSIV Socket is more comfortable than the Ischial Containment (IC) socket.
- **Aim 2:** To demonstrate if the NU-FlexSIV Socket results in better functional performance than the IC socket.
- **Aim 3:** To demonstrate if the NU-FlexSIV Socket will result in better quality of life and "satisfaction with device" (i.e. prosthesis) than the IC socket.

Approach

The overall objective is to provide a more comfortable and functional prosthetic socket for persons with unilateral transfemoral amputation that will ultimately improve their quality of life. This is an assessor-blinded prospective randomized cross-over trial wherein 30 participants will be randomized to using two socket conditions (i.e., NU-FlexSIV or IC). The end points are socket comfort and functional and patient reported performance measures which will be assessed at baseline, 3 and 6 weeks for each socket.



Study is underway. Five subjects are currently being tested with five more enrolled and waiting to begin.

Timeline and Cost

Activities CY	16	17	18
Major Task 1 Recruit 10 subjects per year			
Major Task 2 Fabricate sockets			
Major Task 3 Collect data			
Major Task 4 – Process and analyze data			
Estimated Budget ($K)	**$454K**	**$432K**	**$440K**

Updated: 10/29/16

CY16 Goals

☑IRB approvals (NU, VA, HRPO), clinical trial registration
☑ Recruit and test 10 subjects (underway)

CY17 Goals

☐ Recruit and test 10 subjects

CY18 Goals

☐ Recruit and test 10 subjects
☐ Final analysis and publication

Comments/Challenges/Issues/Concerns

While kicking off the project was slower than planned, we have caught up in terms of subject enrollment.

Budget Expenditure to Date

Projected Expenditure: $454,163
Actual Expenditure: $179,489*
*does not include obligated expenses for year 1